MEETING NOTES

EUROPEAN CARTON MAKERS ASSOCIATION

Food Safety Committee

Date:	**Time:**	**Venue: ONLINE TEAMS**
19 02 2024	10h00 - 12h00 CET	

Chairman: Mike Turner (ECMA MD) [MT]

Participants: Michael Avemarg (Van Genechten Packaging) [MA], Sigrid Gerold (Mayr Melnhof Packaging) [SG], Mathilde Gros (Graphic Packaging) [MG], Eliza Konecka-Matyjek (WestRock) [EK], Paolo Minichini (SEDA) [PM], Elaine Murray (WestRock) [EM], Carola Poggenpohl (Mayr Melnhof Packaging) [CP], Christian Schiffers (FFI) [CS], Caroline Seguin (Mayr Melnhof Packaging) [CSG], Helena Moring Vepsalainen (Mesta Group) [HV], Jan Cardon (ECMA) [JC]

Guest: Mike Simoni (EuPIA Chairman PIFood Printing Inks for Food Packaging - Sun Chemical) [MS]

Apologized: Carmine Iuvone (SEDA)

1. Introduction and welcome.

Mike Turner welcomed all participants, especially Mike Simoni, and opened the meeting around 10h00.
According to good legal practice, reference is made to the ECMA Antitrust Guidelines which had been prepared by ECMA's legal attorneys. The proceedings of this meeting would be in accordance with these guidelines. A statement summarizing these Guidelines was read out. They are designed to ensure ECMA meetings' compliance with the legal framework as set out in article 101 of the Treaty on the Functioning of the European Union ("TFEU"), which prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market. It was stressed that individual company data other than those publicly available will, under no circumstances, be made public during the meeting. The purpose of the discussions would not be to identify market related information regarding a particular company but to identify general trends and market developments to the benefit of all those concerned.

A short round of introductions is made and also Helena Moring Vepsalainen is especially welcomed as a new member of the FS Committee.

2. Exchange with EuPIA See meeting preparation: p. 5-19.

2.1 Information exchange between ink manufacturers and carton makers.
To introduce the discussion on a number of topics to cover, reference is made to the outcome of a member survey from March 2022 and what is included in the latest version of the ECMA supplier's questionnaire.
The outcome of the survey is indicating the EuPIA GMP is very well known and followed, which means the suppliers are also following the broader
EuPIA guidance on food safety.

Information is shared on the restricted intentionally used substances for which further compliance work needs to be performed, with nevertheless some hesitation when it comes to the concentrations in the inks.
For converters it is however unclear if the obtained lists do contain all substances which may potentially migrate.
A weak area in the information exchange are the used not listed self-evaluated substances.
The identity of those self-evaluated substances, the self-derived restrictions, the applied risk assessment method and the concentrations are often not given, which is in contradiction with the EuPIA NLS/NIAS note (p11) "The statement of composition shall contain relevant information about potential migrating known NIAS and NLS …"
The ECMA supplier questionnaire is covering after the section on legal compliance, the need to obtain accurate information on all IAS.
Comments made:

- [MS] suggested to streamline the legal compliance section in the questionnaire. Compliance with 1935/2004 (1) and the CoE resolution (3) may be combined. Complying with the EuPIA GMP (5) means, 2023/2006 (2) is fulfilled.

Ink suppliers are not able to declare compliance with legislations such as the German or Swiss Ordinances. Compliance depends on the ink layer thickness, the pack geometry, the pack structure. The ink suppliers deliver the necessary regulatory information, to make as a converter the compliance assessment.

- [MG] insisted on the need to obtain appropriate compliance information, "indeed not in a compliance yes/no mode". The ink supplier needs to work with the existing substance lists.

[MS] The combination of compliance with the FCFR 1935/2004 with the substance lists required in the questionnaire is probably what is asked for.

- [MG] The detailed questions covered in the questionnaire is what the customers want to obtain. It may be helpful if the ink supplier would also be in direct contact with certain customers.

[MS] Direct contacts with food customers are conceivable, but the existing PIJITF platform provides background on the information which needs to be made available. In the Packaging Ink Joint Industry Taskforce, the raw materials, the ink industry, the converters and FoodDrinkEurope are represented.

- The proposal to change the wording for (4) into "Compositional compliance with other specified legislations" is accepted. [SG]
- [MS] suggests to reword the start of the IAS section in the questionnaire into "All regulated relevant substances, including all monomers and additives … "are present …

This indicates better it is about everything.
If not listed self-evaluated substances are present, they are almost always related to the pigment surface coatings.
Ink suppliers are often prepared to provide information on the NLS with details on the performed risk assessment, but this cannot be summarised in a small Excell box. It seems better to write "can be provided separately."

- [MS] For the concentrations in the inks, the solvent is evaporating, but residual levels may remain present. This is however converter controlled. Similarly for the reactive inks, the suppliers can provide the concentrations in the delivered ink, but not the concentration in the cured ink film. Correct to a certain extent, but converters expect - when suppliers are selling inks into the carton sector - tests have been done confirming compliance, in case the inks are used and cured in a correct way. [MS] Is reasonable. Some individual ink suppliers will refer to performed company tests demonstrating compliance when correctly applied.

- [CS] The ink suppliers need to take in account the market structure! The companies represented in the FS Committee are the absolute experts on food safety from 7-8 companies, together representing roughly 50% of the market. Aside those companies there are however 99% other SME companies, less aware of the shared responsibilities between suppliers and converters and statements made for liability reasons. Towards the SME companies it is for the ink (and other) suppliers not sufficient to declare "we can't take responsibility for the dry ink layer because the curing is converter controlled."

Suppliers need to help converters to deliver with their products complaint cartons.
Converters need an active supporting role from their suppliers. If you use our material in such a way, your cartons will comply.
[MS] We, ink manufacturers and carton makers have all an interest in protecting consumers and EuPIA has worked hard to develop guidance on information exchange.
Besides those efforts, most ink manufacturers provide training for customers. Big customers are typically asking "What will happen next?" while SME companies come with "What do I have to do?" The ink suppliers (Sun Chemical, Flint, Siegwerk, Huber, INX …) can well handle both types of requests. The message to have to the SME carton makers is "to go to their ink supplier and ask what they should do"!

Non intentionally used substances.

For all supplier categories - according to the member survey - the provided information is not sufficient on NIAS.

- [MS] The amount of NIAS which may appear by far exceeds the IAS, and here the risk assessment is even more important. All EuPIA members should provide voluntarily without converters asking, information on NIAS.
- In the course of the discussion, it was identified that the reason for this "missing" information on NIAS is the delivery of lists of substances without a clear labelling (IAS/NIAS) [MS/CP]

[MG] This split is however needed. Customers are asking converters after their NIAS risk assessment. It helps in the discussion, if a substance is found and is not on the declared well labelled IAS list. This already indicates it is probably a NIAS …
The information which can be provided is also different, concentrations can be given for IAS, while for NIAS it will only be possible to give indications on expected concentration levels.
[MS] Most NIAS are known. If AZO pigments are used, some level of PAA's will be present. …
[EK] Customers expect the differentiation between the IAS substances, the NIAS and the dual use substances.
[MS] reports back to the EuPIA PIFood committee.

Use instructions

The ECMA member survey indicated ink suppliers are providing partly use instructions, what is for instance often missing is the maximum amount of ink which can be used around 1 kg of food.
The latest suppliers questionnaire version is now also containing more precise questions related to the allowed food in pack treatment and knowledge sharing on the chemicals to avoid in the other FCMs carton makers are using, in view of the reactions which may happen.

- [MS] The use instructions should be covered to a large extent in the technical datasheets. It is currently an individual ink manufacturer's decision to share with customers for a given ink layer thickness, the maximum compliant area-volume ratio to remain compliant.

This is a useful tool. Some suppliers will make this type of WCC. Within EuPIA there are all types of suppliers and the association can't set too high burdens.
Also here, the recommendation is to go back to your individual ink manufacturer and to ask for a WCC calculation. This is business to business communication.

Other useful information.

The ECMA suppliers questionnaire, requests in this part,

statements on well-known concerns (MO, PFAS, BPA …) and highlights also any changes in the composition need to be well-communicated, as covered in the EuPIA GMP section on change management.

- [MS] PTFE is pretty much the only source for PFAS in inks. 99,9 % of the PFAS in printing inks is PTFE wax, and those waxes with a high molecular weight are not the most of concern. Only very small residual amounts of the low molecular weight PFOA may be present.

Are those PFAS really necessary in inks? The answer is no, they can be formulated out and replaced by waxes which do not pose regulatory concerns.

Carton makers need to have a discussion and if the supplier is indicating, PFAS are still used, the question needs to be, "how long it will take to have PFAS out" without a higher cost.

Historically many inks contained PTFE, but the same slip properties can be achieved without.

PFAS is more an issue in wet strength, in additives, in plastics as an extrusion aid and in food processing equipment.

In inks, the PFAS are not essential. Many customers made already PFAS free requests. As an indication, for the currently delivered inks to carton manufacturers already 85% is PFAS free, and raising the percentage to 99% is not a problem, just requires discussion. The capacity and the alternatives are there. The last percentage may be more problematic. In a small number of applications, the PFAS may be needed.

- BPA is causing a problem as far as BPA is still used. [MS] has no information to which extent BPA is still present in the inks supplied to the carton sector.

An EuPIA survey from some time ago for the labels, showed 75% of the ink manufacturers were no longer using BPA containing resins. To be precise it is not about the presence of BPA, it is all about the polymeric resins that are formed using BPA monomers.

Under certain conditions, particularly high temperature conditions, the material can depolymerise creating BPA. What carton makers should be asking for is not "BPA free", but "not containing BPA based polymers".

If 75% is already not containing BPA, the other 25% should easily be able to make the switch, but customers should make clear what they are asking for.

The concern is not only BPA, different other bisphenols have the same toxicological properties (BPS …), which means one should require "bisphenol free - not containing bisphenol based polymers."

2.2 Specific questions related to the EuPIA Guidance documents.

- No questions were raised.
- [MS] shared it is the intention to come later this year with an update for the EuPIA GMP. The current version is from 2016 and extra elements need to be added.

2.3 Testing conditions LT @ RT

From the previous FS Com meeting, the table with the testing conditions included in the EuPIA Guidance and a first reply obtained from [MS] on appropriate testing conditions for paper and board, are again briefly presented.

- [MS] mentioned EuPIA has spent 70 000 € for a study with Fraunhofer. A vast amount of information is available in this study with thousands or even more data points.

Ethanol 95% is not appropriate for testing paper and board. You just end up with a mash.

The Fraunhofer study indicated 10 days @ 40 °C with MPPO is a good approach for 6 months @ RT, but this is not sufficient for a longer storage time. Equilibrium is not reached in 10 days. To perform an accelerated test for a storage time up to 1 year it is therefore need to have a longer contact time of 30 days.

- With reference to the paragraph 4.4 of the EuPIA guidance on migration testing, to which extent can migration modelling help, once test results for 10 days @ 40 °C are available? (Rainer Brandsh - SAE + Algorithmics / Olivier Vitrac - French National Institute for Agriculture, Food and Environment INRAE)

[MS] is in favour of modelling and combining both analytical testing and modelling is a good approach. Is working with Rainer Brandsh.

- Availability of the Fraunhofer study? [EK]

[MS] No, is a study commissioned by EuPIA, but a scientific paper on the outcome will come. The study was complicated, as non Fickian behaviour was found, not according to Ficks law of diffusion.

- Were the tests indicating 10 days @ 40 °C is not sufficient, done for a paper substrate? [SG]

[MS] Yes, the Fraunhofer study was over ambitious. Tests were performed for 3 different substrates (Paperboard, PE and PP) and for lots of different substances.
An ink was made containing all those substances and was printed. Fraunhofer did the testing. The interpretation is difficult, but we start to understand.

- The obtained information in November indicated 30 days @ 40 °C is a good accelerated test for storage up to 1 year at RT, what above 1 year?

[MS] The indications given come from the EuPIA Analytical Expert Team, this is a separate working group created within EuPIA.
[MS] will ask for 2-5 years and EuPIA will come with an update of the Migration Testing Guidance. Certain labs just continue to test according to the Plastics Regulation and as mentioned previously certain testing conditions are for paper and board just leading to a mash. We must come with something realistic.
Part of the Fraunhofer study there has also been migration testing into real foods.
[EK] insisted to obtain more information about appropriate testing conditions for the longer storage times, above 1 year!

2.4 Mineral oil requirements in France.

[MS] The note by [MS] and Lionel Spack (Nestlé) announced in PIJITF should already have been circulated. The text is finished.
For 3 reasons it is not possible to confirm compliance with the levels in the French legislation (limits 2025):
. For printed articles it is not possible to identify the source of the mineral oils, although the legislation is only about the inks.
. Substances can easily be misidentified as mineral oils: paraffin waxes, low molecular weight components of PE waxes … are from a regulatory perspective no mineral oils.
. The detection limits are not there to verify the 2025 requirements.
All this means it is not easily possible to demonstrate compliance by analytical means, but it is possible by a chain of custody approach. Based on the information from suppliers, (no mineral oils present), compliance can be confirmed and this can be communicated further down in the supply chain.

2.5 How to handle NIAS

Aside the individual bilateral information sharing on the present NIAS, ECMA tries to develop a generic indicative lists of NIAS per FCM material. Would EuPIA be able to deliver such a list for the ink categories the carton sector is using?
[MS] The individual EuPIA members should be giving accurate information on NIAS. If the ECMA members would share those lists, such a list can be developed.
[CSG] Certainly a number of ink suppliers have as their first rule in their statements of composition, the included information can not be shared! The information can even be password protected.
[MS] The statement of composition contains confidential information and is used for regulatory purposes. How such a project would be handled in EuPIA, is to work with an external consultant. If the members are sending the information anonymously, a generic list can easily be developed for instance with all NIAS which are declared by 3 members.

If the setup is done this way, there should be no concern for EuPIA. This way reverse engineering on the composition is difficult.

2.6 UTC limits in pigments.

ECMA has been alerted on the UTC levels for PCBs currently discussed in the POPs Regulation Expert Committee.

One of the slides presented in a previous FS Com meeting provided an overview of the pigments which would not be allowed any longer in case maximum levels of 10/5/1ppm would be adopted, but it seems the committee is now even discussing a level of 0,1 ppm.

Which would be the impact on the inks the carton sector is applying?

Are there pigments available with lower UTC PCB levels?

From another angle, PCBs are an issue in recycled P&B. EN-ISO 15318 is about testing for PCBs and a maximum permitted content for PCBs in paper and board is included in national legislation (Italy/France).

- [MS] If the current proposals would go through, we would end up with an extremely low limit of 0,1 ppm after six years. If this would come into force, it would be catastrophic, it would directly affect 80% of the products the ink industry supplies to carton makers.

The good news is, that this is 6 years away and that there is room for regulatory advocacy, e.g. via the PIJITF.

Over the years the PCB levels will come down. Depending on the colour indexes, certain manufacturers can already deliver pigments with less PCBs than others. Stricter limits would reduce the sourcing possibilities, but 0,1 % is not achievable. A balance must be found between consumer and environmental safety, without completely destroying the ink industry.

- In a best practices approach, what can be achieved 5/1 ppm?

[MS] Depends on the colour index. ETAD, the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers, is probably a little bit defensive, as they have to defend all their members and not only those with the lowest impurity pigments.

This needs to be a topic in any coming PIJITF meeting.

Lower indicative levels can only be given, colour index by colour index.

2.7 Allergens in printing powders.

Reference is made to the ECMA GMP guidance in relation to allergens and to a case from Germany where a carton maker was blamed by a food customer for not communicating on the presence of wheat in a printing powder.

Is a declaration from the supplier “gluten free because below 20 ppm”, sufficient or is there an obligation to communicate on traces?

- [MS] There is only a need to communicate if there is a potential concern. Toxicological expertise is needed. At which threshold there is a risk of an allergenic reaction? Many ink manufacturers have in between a toxicologist in their team.

If the concentration of the allergen is far below the levels which may cause a concern, there is no need to communicate. Compliance is assumed. If levels come closer to 20 ppm, it is important to communicate. Toxicological input is required!

[CSG] Unfortunately the market context is different. Customers ask to communicate on traces … If you think some allergens may be present, you have to declare this. It is not up to the ink supplier to decide if communication is needed. Carton makers are using different materials and to verify compliance all sources need to be added up. Also, in a BRC context information on any presence is needed. We need to be fully aware.

[MS] In the own company a regulatory cut-off is used. If the levels which may be present remain 100 times below the level of regulatory concern, there is no need to declare. Such a cut off helps to avoid overwhelming and too complicated information (reference to comment CS).

[CGS] Can this be confirmed, the safety factor of 100 and how this in combination with other FCMs cannot lead to non-compliance?

[MS] There is always the option to go back to your supplier, and - if not in the Statement of Composition - to ask for more.
- Alternatives for wheat?

[MS] will ask.
[CSG] yes exists, certain powders are based on potatoes. Performance?

Hereafter the very useful exchange is closed with special thanks to Mike Simoni. In the closing comments [MS] insisted again on the need for regulatory advocacy, the value of the PIJITF and the value of also having such a bilateral exchange opportunities.

3. Approval minutes and short follow up from the Food Safety Committee 13/12/23

No comments are made.
The minutes are considered as approved.

4. Tour de table on specific food safety concerns and developments.

See meeting preparation p20-21.
- In de RASFF portal, mainly Germany continues to notify contaminations with mineral oils (Food 5 / FCM 1) and France continues to check for the phthalates (3 FCM).
- No new issues in the market were reported.

5. Legal food safety developments.

See meeting preparation p 22-27.
Review EU FCM legislation.
E&Y and DG Sante organise on the 15/03 a workshop on the developed policy options to support an IT infrastructure required for information exchange, compliance verification and facilitating compliance controls. Also company experts are invited to participate. (See mail FS Com 12/02)
Draft regulation on BPA
In essence the regulation intends to ban BPA and the other bisphenols with a same toxicological profile in food contact materials and articles within the scope of the FCFR 1935/2004.
The draft recognises unintentional BPA contaminations cannot be fully controlled in recycled materials, but that in the light of the circular economy it is neither practical nor proportionate to prohibit the presence of BPA in recycled materials.
The text contains however a monitoring obligation.
Manufacturers will have to carry out a monitoring on 5% of the batches, work on reduction/ elimination and report to the authorities.
Comments can be introduced until the 8/03.
- [CS] In relation to the monitoring, who is meant with “the producer”? In the FCFR 1935/2004, the final FCM products need to be safe.

On the monitoring of BPA in recycled paper and board, the mills should monitor. They can avoid the use of more BPA contaminated sources of PfR.
- [SG] Also not sure who is responsible for the monitoring. “The manufacturer of food contact materials and articles.” Materials could be understood as the substrate manufacturers, but what about the articles?

[SG] supports the view, this monitoring can best be done at the mill level, but not enough testing capacity is available to perform all those monitoring tests (5% …)! The input PfR is not tested on the presence of BPA. For the board produced a number of controls are done internally, others externally.

The BPA checks are performed by external labs, not in line, especially with the levels authorities are now talking about. To obtain the results from the external labs it can take 2-3 months.

- It is agreed to introduce as ECMA comments in the consultation process.

[CS] suggests to be in contact with CEPI as they intend also to comment.

Swiss Printing Ink Ordinance updated as of 1/02

[MG] shared information on the update.

List B will be deleted. A Declaration of Compliance (DOC) will be required in Switzerland and the authorities will come with a guidance document.

6. ECMA Statement on testing conditions.

See meeting preparation p 28-34.

Briefly some extra background is presented out of the JRC publication "Testing conditions for kitchenware articles in contact with foodstuffs, plastics, metals, silicone & rubber, paper and board. (4th edition 2023).

The prescribed testing conditions vary for RT between 10 days 40 °C and 10 days 60 °C, depending on the contact time (up to 30 days / ≤6 months / >6 months) and if the equilibrium is reached…

Eva Lindström (SCA - Author testing chapter CEPI/CITPA Guideline) indicated, 40 °C is already accelerating the migration compared to 25 °C, tests for the board on its own were done proving equilibrium is reached after 10 days, the migration in paper and board is happening much faster as in plastics and how some additional tests may be needed.

The draft statement (circulated 7/02 and 8/02) is briefly presented.

Comments made:

- [EK] It would strengthen the statement if EuPIA would allow we make in the wording reference to the study done by Fraunhofer, that the testing conditions 40 °C 30 days are based on an EuPIA study done by Fraunhofer. Very important to obtain also the confirmation those testing conditions do also cover 2-3 years of storage time.
- [MA] It would in addition be valuable to obtain also feedback for the board from PTS, thus our statement would be based on even more well recognised expert opinions. (Fraunhofer and PTS)
- [EK] shares how the own company is performing tests for just a few chemicals (still the acrylates) with their ink supplier and an accredited external lab, for 63 days at 40 °C. Interesting findings will be shared.

With the integration of the comments made, the statement is considered as adopted. [The final version will be circulated to the FS Com, before publication.]

7. Update sustainability related topics.

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8 Miscellaneous

- ECMA is involved in the PTS paper and board for food contact conference.
- The next FS Committee meeting is scheduled on the 19/04 (10h00-12h00). The visit of FERA will take place on the 23/04.

Hereafter all agenda items were covered and the Chairman closed the meeting around 12h00.
All participants were thanked for their attendance and contribution in the discussions.